



DEPARTMENT OF HEALTH
OFFICE SURGERY INSPECTION FORM
LEVEL II & III

4052 BALD CYPRESS WAY, BIN #C03

TALLAHASSEE, FLORIDA 32399-3253

INSPECTION AUTHORITY - CHAPTER 458.309, FLORIDA STATUTES;
RULE 64B8-9.0091, FLORIDA ADMINISTRATIVE CODE

Florida
HEALTH

see attached

NAME OF OFFICE SURGERY FACILITY			DATE OF INSPECTION								
STREET ADDRESS			PHYSICIAN NAME(S)								
TELEPHONE			COUNTY								
CITY			STATE/ZIP								
Vanidades Cosmetic Surgery - Laser			OSR #350								
8506 SW 8th Street			Jonathan Fiseler MD								
305-262-6070			Rami Ghurani, MD								
Miami			Rafael Salas MD								
FL 33144			NE 89865								
NE 106242											
Requirement for Physician Office Registration			YES	NO	NA	Requirements for Level II Office Surgery			YES	NO	NA
1. The physician(s) is registered to perform office-based surgery with the Board of Medicine[64B8-9.0091(f)]			✓			22. Transfer Agreement Required or Hospital Staff Privileges [64B8-9.0094(b), FAC]			✓		
2. The physician(s) office is not accredited with a national accrediting organization or Board approved organization			✓			23. Compliance with Training Requirements[64B8-9.0094(b)(2), FAC]			✓		
3. The physician(s) performs surgery as defined in the Board [64B8-9.0091(a), FAC]			see below			24. Compliance with Basic Life Support Certification[64B8-9.0094(b)(2), FAC]			✓		
4. The surgeon(s) is an active licensed physician(s) in the State of Florida[64B8-9.0091(b), FAC]			✓			25. Compliance with Advanced Cardiac Life Support Certification[64B8-9.0094(b)(2), FAC]			✓		
5. The equipment meets the current performance standards[64B8-9.0091(c), FAC]			✓			26. Compliance with Equipment and Supplies Required[64B8-9.0094(b)(3), FAC]			✓		
6a. The surgery is being performed outside a hospital, ambulatory surgical center, abortion clinic or other medical facility licensed by the Department of Health or the Agency for Health Care Administration[64B8-9.0091(d), FAC]			✓			27. Compliance with Crash Cart Resuscitative Medications[64B8-9.0094(b)(3a), FAC]			✓		
6b. The surgery is being performed pursuant to definition of office surgery as described in 64B8-9.0091(d)			see below			28. Compliance with Anesthesia Provider[64B8-9.0094(b)(4), FAC]			✓		
General Requirements for Office Surgery						29. Compliance with Additional Assistance[64B8-9.0094(b)(4), FAC]			✓		
7. Compliance with pre-operative Evaluation[64B8-9.0092(a), FAC]				✓		30. Compliance with Recovery Monitoring[64B8-9.0094(b)(4), FAC]			✓		
8. Compliance with Patient/Procedures Records[64B8-9.0092(a), FAC]				✓		Requirements for Level III (Include the requirement for level II Office surgery as well as the requirements outlined)					
9. Compliance with Informed Consent[64B8-9.0092(a), FAC]				✓		31. Compliance with the American Society of Anesthesiologist's Classifications for appropriate candidates for level III office surgery[64B8-9.0094(b)(5), FAC]			✓		
10. Compliance with Surgical Logs[64B8-9.0092(c), FAC]			✓			32. Compliance with Additional Training Requirements[64B8-9.0094(b)(1), FAC]			✓		
11. Compliance with liposuction procedures[64B8-9.0092(d), FAC]			✓			33. Compliance with Emergency Procedures[64B8-9.0094(b)(2), FAC]			✓		
12. Compliance with liposuction combination procedures[64B8-9.0092(e), FAC]			✓			34. Compliance with Additional Equipment and Supplies[64B8-9.0094(b)(3), FAC]			✓		
13. Compliance with Elective Cosmetic and Plastic Surgery Procedures[64B8-9.0092(f), FAC]			✓			35. Compliance with Anesthesia Provider[64B8-9.0094(b)(4), FAC]			✓		
14. Compliance with overnight stays except for elective cosmetic and plastic surgery[64B8-9.0092(f), FAC]					✓	36. Compliance with Additional Assistance of Other Personnel Required[64B8-9.0094(b)(4), FAC]			✓		
15. Compliance with overnight stays in relation to any surgical procedure[64B8-9.0092(h), FAC]					✓	Miscellaneous (Please Specify)					
16. Compliance with post-operative care[64B8-9.0092(h), FAC]			✓			Siddharth Bass, MD			NE 79410		
17. Compliance with anesthetic monitoring[64B8-9.0092(g), FAC]			✓			Anthony Hasan, MD			NE 78230		
18. Compliance with policy and procedures manual[64B8-9.0092(i), FAC]			✓			Dantrolene 36 vials + stryke 11oz					
19. Compliance with risk management program[64B8-9.0092(j), FAC]			✓								
20. Compliance with adverse incident reporting[64B8-9.0092(k), FAC]			✓								
21. Compliance with signage[64B8-9.0092(l), FAC]			✓								

Comments: Last inspection 10/12. Five physicians are approved to perform level II + III plastic/cosmetic surgery. The office is doing business as: DBA Vanity Cosmetic Surgery - Office needs to submit name change to the DOH. 7) On several chart the "immediate prep" form was completed but not signed by surgeon. 8) 4 of 8 charts reviewed ASA was not documented by surgeon or anesthesia provider. 9) 4 of 8 charts reviewed follow up appt was on chart, scribbled by an MA & no physician signature. 2 of 8 charts were missing on op/dictation note. 9) the patient completes the procedure to be performed on the consent form. They do not write the procedure to be completed performed. I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Signature of Responsible Party

Date

Investigator

Date

Revised 07-2013

One consent form stated procedure to be performed "personal".

11) Majority of the charts reviewed the amount of Lidocaine used was not

64B8-9.0091 Requirement for Physician Office Registration;

Inspection or Accreditation

If the office is determined to be in noncompliance, the physician shall be notified and shall be given a written statement at the time of inspection. Such written notice shall specify the deficiencies. Unless the deficiencies constitute an immediate and imminent danger to the public, the physician shall be given 30 days from the date of inspection to correct any documented deficiencies and notify the Department of corrective action. Upon written notification from the physician that all deficiencies have been corrected, the Department is authorized to re-inspect for compliance.

I have read and understand the above Section of Rule 64B8-9.0091, F.A.C.



Signature of Facility Representative

- 11) The amount (ml's) of Lidocaine not documented.
- 12) Two charts reviewed had a discrepancy of amt of SNF removed (see attached.)
- 16) No documentation of who the patient was discharged to. Sometimes the patient is discharged by cab to hotel.
- 19) No quarterly Risk management meeting minutes, only Annual meeting.
- 20) Three adverse incidents reported since last inspection. They were reported within the 15 day timeframe.
- 23) Three surgeons are boarded in plastics. One is boarded in cosmetics. One is a general surgeon, not boarded. No documentation of plastics/ cosmetic training.
- 25) One PACU RN does not have an ACLS certification
- 31) See #7
- * Submit CRNA protocols to DOT. (some are)
- * Submit an updated state/nurse timeline list to Ben

#1

Summary

OSR 350

Vanidades Cosmetic Surgery-Laser
DBA "Vanity Cosmetic Center"

- This office has 3 functional DR's.
- The office has a reported death in 7/13
- One physician is not boarded. He is a general surgeon. No evidence/documentation of plastic/cosmetic training. He has been performing these procedures for years and practices at many offices.

Charts Reviewed:

- ① 11/8/13 11870 LE ASA I Level III 29yo 132#/60kg
Lipo abd, flanks, back + bra-roll (12 areas)
C fat tx to buttocks

(Dr. Fisher)

Inf Klein solution: 3000 Asp: 4100 SNF: 2850

Fat tx (R) 960cc (L) 1020cc

- No documentation of Klein solution mixture or the amount of Lidocaine used.
- Patient was in PACU from 1445 - 2330. The patient was then transferred to the hospital DT hypotension, dizziness.
- The RN received verbal telephone orders from the surgeon to transfer. Orders not signed by physician.

- ② 7/11/13 MC ASA II Level III 51yo 165#/75kg
Lipo C fat tx

(Dr. Hasan)

KS: 4000 Asp: 4000 SNF 3200Fat tx 600cc per site
Lido: 500mg/L = 26.6mg/kg used total 1200 tx

(medical clearance obtained)

#2

OSL 350

③ 11/7/13 37969 AE ASA II Level III 47yo 193# / 89.5 Kg.
Lipo X 12 areas (medical clearance obtained)

- Procedure was aborted 2° to ↓ SATs. Patient (Dr. Hasan) was transferred to the hospital. Dx: Pulmonary edema
- Op note not in chart.

④ 11/19/13 37672 ZF ASA II Level III 33yo 136# / 61.8 Kg.

Lipo (12 areas) C fat tx to buttocks * Pt has no medical Hx. Should be ASA I.

Dr. Fisher) KS: 4000 Asp: 4200 SNF 2350 Lido: 250mg/L = 16.18mg/Kg used Fat tx: 475 @ 1090 @

- Patient was discharged to ~~cab~~ hotel with a cab driver. No responsible adult to stay with patient.

⑤ 11/19/13 37635 ASA I Level III 40yo 140# / 63.6 Kg

Lipo C fat tx to buttocks (med. clearance obtained)

* Dr. Hasan) KS: 4000 Asp: 5000 ^{Op note} SNF 4000 * DR record says 5000 SNF

- No documentation of how much Lido was used
- Fat tx 540cc each side
- No ASA marked by anesthesiologist or MD on chart. (documented)
- Follow up assessment documented by a MA. It did not address surgical sites. No MD signature on F/U. No indication the patient was seen by a physician.

Hasan) ⑥ 11/18/13 YG ASA II Level III 29yo 190# / 86.3 Kg
Liposuction

KS: 4000 Asp: 5000 SNF 4000

Lido: 560mg/L 23.1mg/Kg used

#3

DSR 350

Cont.

- ⑥ No ASA documented by anesthesiologist or MD on chart.
 - Follow up assessment/visit was documented by an MA.
 - It did not address surgical sites. No MD signature.
 - No indication/documentation the patient was seen by a Dr.

Dr. Salas

- ⑦ 7/15/13 ASA II Level III 33yo 145^{lb}/65.9Kg.
 - Lipo (12 areas) + Fat tx to buttocks
 - RS: 4000 Asp: 4000 SNF: 3000 fat tx 780cc each side
 - Lido: 250mg/L = 15.17mg/Kg used
 - PT was discharged to hotel via cab. No adult to stay with patient.

~~None~~

Pharm

- ⑧ 7/11/13 AA 31510 ASA II Level III 26yo 224^{lb}/101.8Kg.
 - Lipo + Abdominoplasty
 - RS: 1000 Asp 1500 SNF 1000
 - Lido: 300mg/L = 2.9mg/Kg used

* This office discharges patients to a hotel via cab. If the patient doesn't have anyone to take care of them postop. Occasionally, the office will arrange someone (MA, LPN) to stay with patient at the hotel. Currently the center/office has purchased a house. They are planning on using it as a recovery home. The proposed name for the house will be "Home Away Varsity".

#4

OSP 350

- Consent forms are completed by the patient. Therefore, the consents are incorrect. Many are abbreviated, one stated as procedure performed "personal" others may say Lipo.

WEST DADE SURGERY, D.B.A. VANITY COSMETIC SURGERY
8506 SW 8TH ST
MIAMI, FL 33144

December 16, 2013

Dept of Health
Board of Medicine
4052 Bald Cypress Way, BIN #C03
Tallahassee, FL 32399
Office Surgery Department

RE: PLAN OF CORRECTION:

West Dade Surgery, DBA Vanity Cosmetic Surgery OSR# 350

Location Address: 8506 SW 8 St. Miami, FL. 33144

Date of Inspection: 11-22-2013

Registered Physicians: Dr. Rami Ghurani, ME 89865; Dr. Salas ME 108242; Dr. Jonathan Fischer ME96746 & Dr. Anthony Hasan, ME 78230; Siddharth Bass, MD ME 79410

Conducted by: Deanna K Pfoff, RN. LHCRM

As of November 25, 2013, the office surgery center has begun implementing the following deficiencies:

Dr. Ismael Labrador, Administrator/Medical Director of West Dade Surgery, DBA Vanity Cosmetic Surgery is responsible for the corrective action and ongoing compliance.

The administrative staff, RN, surgeons and anesthesia personnel have been in serviced on December 4, 2013 for the following deficiencies and shall maintain compliance with Chapter 458.309 Rule 64B8-9.0091, F.A.C.

1. Attached to this plan of correction is the updated Application with the correct name of the Business.
2. Tag # 7 Compliance with Pre-operative evaluation:
Dr. Ismael Labrador met with his credentialed physicians and discussed the Quality Assurance issues discovered in the immediate preoperative during the inspection have been corrected; these include the physician signature and the documentation of the ASA classification. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.
3. Tag # 8 Compliance with Patient /Procedures records:
 - a. Dr. Ismael Labrador met with his credentialed physicians and discussed the Quality Assurance issues discovered in follow up appointment form during the inspection have been corrected; the Medical assistants will scribe for the physician as long as the physician signs off on each visit. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.
 - b. Dr. Ismael Labrador met with his credentialed physicians and discussed the Quality Assurance issues discovered by having absent Operative notes in the medical record during the inspection have been corrected; those medical records contain a signed operative note by the surgeon. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.

WEST DADE SURGERY, D.B.A. VANITY COSMETIC SURGERY

8506 SW 8TH ST

MIAMI, FL 33144

4. Tag # 9 Compliance with Informed consent:

Dr. Ismael Labrador met with his administrative staff and discussed the Quality Assurance issues discovered in the documentation of the informed consents during the inspection have been corrected: Staff has been made aware that only the staff of the organization are instructed properly document the procedures in the informed consent. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.

5. Tag # 11 Compliance with Liposuction Procedures:

Dr. Ismael Labrador met with his credentialed physicians and discussed the Quality Assurance issues discovered of not properly documenting the correct amount of ml's of Lidocaine during the inspection have been corrected. Dr. Ismael Labrador demonstrated to each credentialed physician where those amounts of Lidocaine (mls) are to be documented in the "operating room record and then that information is transferred correctly in the physician operative report. The purpose is to ensure that no physician exceeds the state mandated amount of 50mg/kg of lidocaine per patient. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.

Tag # 12 Compliance with Liposuction combination procedures; Dr. Ismael Labrador met with his credentialed physicians and discussed the Quality Assurance issues discovered of the discrepancy of the amount of Supernatant Fat (SNF) during the inspection have been corrected. Dr. Ismael Labrador demonstrated to each credentialed physician where the amounts of SNF are to be documented in the "operating room record and then that information is transferred correctly in the physician operative report. The purpose is to ensure that no physician exceeds the state mandated amount of 4000cc of SNF per patient. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.

Tag # 16 Compliance with Post-operative care Dr. Ismael Labrador met with his Registered Nurses and discussed the Quality Assurance issues discovered of not properly documenting to whom the patient is being discharge too during the inspection has been corrected. The RN was documenting Discharge to "home" instead of writing down "spouse" "family member" caregiver" they have been instructed to how to properly document. During the inspection one chart did have the word "hotel" however no patient leaves the premises without an adult present. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.

6. Tag # 19 Compliance with Risk Management: At the present time the organization chooses to perform their risk management minutes on a quarterly basis. It will be the responsibility of Dr. Ismael Labrador to ensure compliance by conducting and documenting the quarterly Risk Management minutes.

WEST DADE SURGERY, D.B.A. VANITY COSMETIC SURGERY
8506 SW 8TH ST
MIAMI, FL 33144

7. Tag # 20 Compliance with adverse incident compliance: The center had three adverse incidents since the last inspection. All of the adverse incidents were reported to the Dept of Health within the requested time frame of fifteen days.
8. Tag#23 Hospital Privileges Dr. Hasan ME 78230 Board of Cosmetic Surgery has expired. Dr. Bass ME 79410 the general surgeon does not have a board in Plastics. however attached are his training credentials for plastics and/or cosmetic procedures. It will be the responsibilities of Ismael Labrador, Administrator. See attached document

Tag # 25 Compliance with ACLS certification PACU Nurse has updated her file and she has a current ACLS card. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance. See attached copy of ACLS card.

9. Tag # 31 Compliance with American Society of Anesthesiologist's Classification for appropriate candidate for Level III office surgery; Dr. Ismael Labrador met with his credentialed CRNAs & MD anesthesiologist and the Quality Assurance issues discovered of the lack of documentation of the ASA classification during the inspection have been corrected. It was made aware to each credentialed staff member the importance to document ASA classification on their anesthesia form. There must be communication between both the surgeon and anesthesia personnel on what ASA Classification is best for the patient. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.
10. All registered CRNAs have a signed protocol with the surgeons. The CRNAs have submitted to the Dept of Health their signed Protocol detailing their supervising physician. It will be the responsibilities of Ismael Labrador, MD, administrator in maintaining the ongoing compliance.
11. On the day of the inspection we clarified with the inspector our current staff. We are notifying the State that based on our database the following **registered physicians** are **No Longer** working at our facility. Enrique Gomez Daniel Careaga. John Nees, Orlando Llorente, Camile Chavez, Jeremy Ecksterin, Carlos Wiergering, Raul Rodriguez, Arnaldo Valls, and Jean Paul Font. Please be advised we have notified the State DOH of these physicians in the past.
12. We are notifying the State that based on our database the following registered physicians and clinical staff that are **currently** working at our facility:

Physicians: Jonathan Fisher, Anthony Hasan, Rafael Salas, Rami Ghurani, Siddarth Bass, Enrique Pelayo, Paul Reily.

CRNA/ARNPs: Jason Vera, Sergio Hernandez, Gabriel Dietsch, Demarko Bazan, Christopher Jorge, Alexandra Cortes, Mario de la Portilla, Lourdes Dieguez, Richard Lauriello, Seng Fook Lam, Jesus del Risco, Justin Jimenez, Miguel Vasallo, Carolina Wilson, Frankie Lima, Monica Gross Ramos, Susana Airala, Roberto Fernandez, Alex

WEST DADE SURGERY, D.B.A. VANITY COSMETIC SURGERY

8506 SW 8TH ST

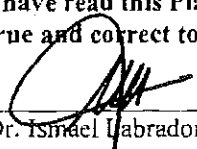
MIAMI, FL 33144

Quinones, Richard Eckert, MD Anesthesia; Jorge Melgen, Eduardo Lorenzo, Carlos Lazalle, Stephane Otmezguine, Osmar Creagh.

RN: Massiel Ruiz, Yuneidys Aguilar, Jessica D. Collazo, Circulators/Medical Assistants: Betsy Reyes, Yunia Calero, Graciela Rodriguez, Adiena Morell, Laura Muriedas.

Surgical Assistants/Technologist: Lester Trastoy, Jorge Jova, Marleivys Romero, Mitdael Moreno, Mario Ledesma, Orlando Cardelles, Alberto Toledo.

I have read this Plan of Correction Report and affirm that the information given herein is true and correct to the best of my knowledge.


Dr. Ismael Labrador, Administrator

10/10/13
Date

Plan of Correction was prepared by Dr. Laura A. Leyva, MBA, HSA, LHCRM, Physician Consultants, Inc. email: Physicianconsult@aol.com



DEPARTMENT OF HEALTH
OFFICE SURGERY INSPECTION FORM
LEVEL II & III

4052 BALD CYPRESS WAY, BIN #C03
TALLAHASSEE, FLORIDA 32399-3253
INSPECTION AUTHORITY - CHAPTER 458.309, FLORIDA STATUTES;
RULE 64B8-9.0091, FLORIDA ADMINISTRATIVE CODE

FLORIDA
HEALTH

NAME OF OFFICE SURGERY FACILITY <u>VANITY COSMETIC SURGERY</u>		DATE OF INSPECTION <u>12-18-14</u>	
STREET ADDRESS <u>8506 SW 8th ST</u>		PHYSICIAN NAME(S) <u>S. BASS</u>	
TELEPHONE <u>305-262-6070</u>		LICENSE NUMBERS <u>ME 78240</u>	
CITY <u>MIAMI</u>		STATE/ZIP <u>FL 33144</u>	
COUNTY <u>MIAMI-DADE</u>		J. FISHER	
STATE/ZIP <u>FL 33144</u>		ME 78230	
		ME 96746	
Requirement for Physician Office Registration			
1. The physician(s) is registered to perform office-based surgery with the Board of Medicine-64B8-9.0091(1)	YES	NO	NA
2. The physician(s) office is not accredited with a national accrediting organization or Board approved organization	YES	NO	NA
3. The physician(s) performs surgery as defined in the Board (64B8-9.0091(a), FAC)	YES	NO	NA
4. The surgeon(s) is an active licensed physician(s) in the State of Florida(64B8-9.0091(b), FAC)	YES	NO	NA
5. The equipment meets the current performance standards(64B8-9.0091(c), FAC)	YES	NO	NA
6a. The surgery is being performed outside a hospital, ambulatory surgical center, abortion clinic or other medical facility licensed by the Department of Health or the Agency for Health Care Administration(64B8-9.0091(d), FAC)	YES	NO	NA
6b. The surgery is being performed pursuant to definition of office surgery as described in 64B8-9.0091(d)	YES	NO	NA
General Requirements for Office Surgery			
7. Compliance with pre-operative Evaluation(64B8-9.0092(a) FAC)	YES	NO	NA
8. Compliance with Patient/Procedures Records(64B8-9.0092(a) FAC)	YES	NO	NA
9. Compliance with Informed Consent(64B8-9.0092(a), FAC)	YES	NO	NA
10. Compliance with Surgical Logs(64B8-9.0092(c), FAC)	YES	NO	NA
11. Compliance with liposuction procedures(64B8-9.0092(d), FAC)	YES	NO	NA
12. Compliance with liposuction combination procedures(64B8-9.0092(e), FAC)	YES	NO	NA
13. Compliance with Elective Cosmetic and Plastic Surgery Procedures(64B8-9.0092(f), FAC)	YES	NO	NA
14. Compliance with overnight stays except for elective cosmetic and plastic surgery(64B8-9.0092(f), FAC)	YES	NO	NA
15. Compliance with overnight stays in relation to any surgical procedure(64B8-9.0092(h), FAC)	YES	NO	NA
16. Compliance with post-operative care(64B8-9.0092(h), FAC)	YES	NO	NA
17. Compliance with anesthetic monitoring(64B8-9.0092(g), FAC)	YES	NO	NA
18. Compliance with policy and procedures manual(64B8-9.0092(i), FAC)	YES	NO	NA
19. Compliance with risk management program(64B8-9.0092(j), FAC)	YES	NO	NA
20. Compliance with adverse incident reporting(64B8-9.0092(k), FAC)	YES	NO	NA
21. Compliance with signage(64B8-9.0092(l), FAC)	YES	NO	NA
Requirements for Level II Office Surgery			
22. Transfer Agreement Required or Hospital Staff Privileges (64B8-9.0094(b), FAC)	YES	NO	NA
23. Compliance with Training Requirements(64B8-9.0094(b)(2), FAC)	YES	NO	NA
24. Compliance with Basic Life Support Certification(64B8-9.0094(b)(2), FAC)	YES	NO	NA
25. Compliance with Advanced Cardiac Life Support Certification(64B8-9.0094(b)(2), FAC)	YES	NO	NA
26. Compliance with Equipment and Supplies Required(64B8-9.0094(b)(3), FAC)	YES	NO	NA
27. Compliance with Crash Cart Resuscitative Medications(64B8-9.0094(b)(3a), FAC)	YES	NO	NA
28. Compliance with Anesthesia Provider(64B8-9.0094(b)(4), FAC)	YES	NO	NA
29. Compliance with Additional Assistance(64B8-9.0094(b)(4), FAC)	YES	NO	NA
30. Compliance with Recovery Monitoring(64B8-9.0094(b)(4), FAC)	YES	NO	NA
Requirements for Level III (Include the requirement for level II Office surgery as well as the requirements outlined)			
31. Compliance with the American Society of Anesthesiologist's Classifications for appropriate candidates for level III office surgery(64B8-9.0096(a)(2), FAC)	YES	NO	NA
32. Compliance with Additional Training Requirements(64B8-9.0096(b)(1), FAC)	YES	NO	NA
33. Compliance with Emergency Procedures(64B8-9.0096(b)(2), FAC)	YES	NO	NA
34. Compliance with Additional Equipment and Supplies(64B8-9.0096(b)(3), FAC)	YES	NO	NA
35. Compliance with Anesthesia Provider(64B8-9.0096(b)(4), FAC)	YES	NO	NA
36. Compliance with Additional Assistance of Other Personnel Required(64B8-9.0096(b)(4), FAC)	YES	NO	NA
Miscellaneous (Please Specify)			
R. CHURANI ME 898105			
R. SALAS ME 108247			
C. LORENTE ME 90844			
J. MA ADDO ME 11935			

Comments: #5 MISSING BIOMEDICAL INSPECTION OF SPORE INCUBATOR AND 2 MONITORS IN PACU. #8 MISSING ANESTHESIA TIME OUT, SOME SURGICAL TIME OUTS MISSING DATE + TIME, NEED TIME ON CONSENTS SIGNED DAY OF SURGERY TO INDICATE PRE-ANESTHESIA. MISSING OPERATIVE REPORTS DR. BASS' CHARTS. #9 ONE SURGICAL CONSENT UNSIGNED 1/13 CHARTS #10 MISSING ADVERSE INCIDENT AND 50% OF SURGICAL LOGS #17 MISSING REMARKS ON 1/13 CHARTS NO ANESTHESIOLOGIST - #19 MISSING QUARTERLY RISK

I have read and have had the inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Signature of Responsible Party
Revised 07-2013

Date

Investigator

Date

Office Surgery Inspection Form

Date 12-18-14

Page Number 2 of 2

Facility Name

Vanity Cosmetic

OSR # 350

MANAGEMENT MEETINGS WITH PHYSICIAN REVIEW, #21 NEED
TO ADD D.O. VERBAGE TO SURGICAL CONSENT FOR DR. McADOO.
#22 MISSING CURRENT HOSPITAL PRIVILEGES FOR DR.
SALAS TO ENABLE HIM TO WORK IN THE OFFICE (PERFORM
SURGERY), #31 MISSING EKG ON 2/13 CHARTS FOR
PATIENTS ASA II 40 AND OLDER, # MISSING LOCAL ANESTHESIA
TOXICITY & FOREIGN BODY PROTOCOLS FOR D.O.S.

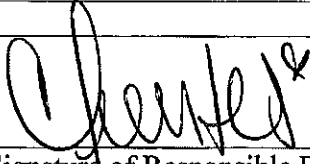
Signature of Responsible Party

Date

Inspector

Date

1/10 charts, missing specific type of anesthesia provider
5/10 charts #10 missing apt codes #18 missing
Quality Assurance Policies #19 missing Quarterly
Meetings + Risk Policies. #26 Laryngoscope Blades
Being washed + reused, must be high level Disinfected
or autoclaved for reuse or use single use disposable.
#27 missing 1.8mg Atropine, Albuterol 2.5mg
and nebulizer mask, missing epinephrine in
1ml vials (has 30ml vial) missing 1% hydrocortisone
100mg #34 missing 1200cc sterile water
without preservative for Dantrolene.


Signature of Responsible Party


Inspector

1/13/16
Date

1-13-16
Date

Vanity Cosmetic Surgery
8506 SW 8TH ST
MIAMI, FL 33144

02/17/2016 1,500.00
ID: 420 Type: F
BT: 3015337
R#: 915040041

Jan 28, 2016

1/13/16

Dept of Health
Board of medicine
4052 Bald Cypress Way, BIM #D03
Tallahassee FL 32399
Office Surgery Department

1514

RE: PLAN OF CORRECTION:

West Dade Surgery, DBA Vanity Cosmetic Surgery OSR# 350

Location Address: 8506 SW 8 St, Miami, FL 33144

Date of Inspection: 1/13/2016

Register physicians: Dr. Jonathan Fisher ME99849, Dr. Rafel Salas ME108242, Dr. Sidd Bass ME79410, Dr. Eric Valladares ME91049, Dr. Arnaldo Valls ME82727

Conducted by: Rachelle Springer, RN LHCRM

As of January 13, 2016 the office surgery center has begun implementing the following deficiencies:

Dr. Ismael Labrador, Administrator/ Medical Director of West Dade Surgery, DBA Vanity Cosmetic Surgery is responsible for the corrective action and ongoing compliance.

The administrative staff, RN, surgeons and anesthesia personnel have been in serviced for the following deficiencies and shall maintain compliance with Chapter 458.309 Rule 64B8-9.0091, F.A.C.

1. Tag #5 Equipment meets the current performance standard: All equipment was re inspected by Mart Medical Equipment a sticker was place an all the missing equipment. It would be the responsibility of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance. See attached document.
2. Tag #8 Compliance with Patient/Procedure Records: Dr. Ismael Labrador and our staff had a meeting to discuss the value of a complete chart, and the importance of the operative reports. Both Dr. Mcadoo, Dr. Salas, and all the other physicians registered in our office have understood. It would be the responsibility of Dr. Ismael Labrador, administration in maintaining the ongoing compliance.
3. Tag #9 Type of anesthesia: Dr. Ismael Labrador has changed the anesthesia consent form, now all anesthesia providers can either circle MD or CRNA to be more specific on anesthesia provider. It would be the responsibility of Dr. Ismael Labrador, administration in maintaining the ongoing compliance.
4. Tag # 10 Missing CPT Codes: All Anesthesia logs were reviewed and re-written by the administration, all CPT codes are on site, and surgery logs are current. It will be the responsibility of Dr. Ismael Labrador, administration in maintaining the ongoing compliance.

5. Tag #18 Compliance with policy and procedures manual: At the present time Vanity chooses to perform quarterly assurance policies with all the doctors and employees on staff. It will be the responsibility of Dr. Ismael Labrador, administration to ensure compliance by conducting and documenting them quarterly.
6. Tag #19 Compliance with risk management program: At the present time the Vanity chooses to perform their risk management minutes on a quarterly basis with physician's review. It will be the responsibility of Dr. Ismael Labrador, administration to ensure compliance by conducting and documenting them quarterly.
7. Tag #26: Compliance with equipment and Supplies Required: Dr. Ismael Labrador met with his staff and discussed the proper ways of washing the instrumentation. At this moment we are only using single use disposable Laryngoscope Blades, staff is aware that they must wash in high level disinfectant or autoclave the Laryngoscopes if they were to re-use. It will be the responsibility of Dr. Ismael Labrador, administration in maintaining the ongoing compliance.
8. Tag# 27 Compliance with Crash Cart Resuscitative Medications: Dr. Ismael Labrador and staff was not aware of the past changes on April 2015. Our administration has order all missing medication in its right dosage. It would be the responsibility of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance. See attached document.
9. Tag#34 Complies with Additional Equipment and Supplies: All missing 1200cc of sterile water without preservative for Dantrolene was order and was placed in the crash cart. It would be the responsibility of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance. See attached picture.

On the day of the inspection we clarified with the inspector our current staff. We are notifying the State that based on our database the following registered physicians and clinical staff that are currently working at our facility:

Physicians: Jonathan Fisher, Rafael Salas, Siddarth Bass, Arnaldo Valls, and Eric Valladares.

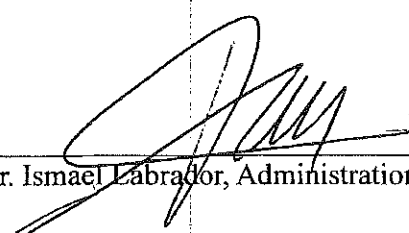
CRNA/ARNPs: Jesus del Risco, Jason Vera, Sergio Hernandez, Gabriel Dietsch, Cristopher Jorge, Alexandra Cortes, lourdes Dieguez, Richard Lauriello, Miguel Vasallo, Carolina Wilson, Christina vera, Carlos de la Hoz, Frankie Lima, Susana Airala, Alex Quinones, Richard Eckert. MD Anesthesia: Jorge Melgen, Carlos Lazalle.

RN: Maritza Rodriguez, Nereida Rodriguez.

Surgical Assistants/Technologist: Cesar Martinez, Mitdael Moreno, Lester Trastoy, Mario Ledesma, Yaite Fernandez, Jose Ramon Jaime, Alberto Toledo, Jorge Fuerte, Klovys Castellanos, Jorge Reyes, Gilberto Iviricu, Marleivys Ramirez, Carlos Diaz

Circulators: Carolina Mourelo, Yanedys Arencibia, Lianys Blain, Graciela Rodriguez, Adiana Morell

I have read this Plan of Correction Report and affirm that the information given herein is true and correct to the best of my knowledge.



Dr. Ismael Labrador, Administration

2/10/2014
Date



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
Office Surgery Center**



File # 420
Insp # 281

NAME Eres Plastic Surgery	PERMIT NUMBER 350	DATE OF INSPECTION 07/11/2017	
DOING BUSINESS AS			
STREET ADDRESS 8506 SW 8TH STREET		TELEPHONE # (305) 262-6070	EXT
CITY MIAMI	COUNTY MIAMI-DADE	STATE/ZIP FL/33144	

License Relations

Office Surgery Registration

CALVA-CERQUEIRA, DANIEL	License # 120264
CHAVEZ, CAMILLE DENISE	License # 68329
FISHER, JONATHAN GEORGE R S	License # 96746
JARIAL, RAVINDER SINGH	License # 9321
PASCUAL, AMARYLLIS	License # 94686
SALAS, RAFAEL EMERICK MD	License # 108242
VALLADARES, ERIC RAUL	License # 91049
VALLS, ARNALDO	License # 82727
VERDEZA, CARLOS MD	License # 97208

Office Surgery Registration

Requirement for Physician Office Registration

1. The physician(s) is registered to perform office-based surgery with the Board of Medicine [64B8-9.0091(1), FAC]	Yes
2. The physician(s) office is not accredited with a national accrediting organization or Board approved organization	No
3. The physician(s) performs surgery as defined in the Board Rule [64B8-9.009(1)(a), FAC]	Yes
4. The surgeon(s) is an active licensed physician(s) in the State of Florida [64B8-9.009(1)(b), FAC]	Yes
5. The physician(s) notified the Department, in writing of any changes to the registration information. [64B8-9.0091(1)(c), FAC]	Yes
6. The registration is posted in the office [64B8-9.0091(1)(d), FAC] <i>Osteopathic standard of care for surgery 64B15-14.007 added to current posting of 64B8-9.009 at time of inspection.</i>	Yes
7. The equipment meets the current performance standards [64B8-9.009(1)(c), FAC]	Yes
8. The surgery is being performed outside a hospital, ambulatory surgical center, abortion clinic or other medical facility licensed by the Department of Health or the Agency for Health Care Administration [64B8-9.009(1)(d), FAC]	Yes
8a. The surgery is being performed pursuant to definition of office surgery as described in 64b8-9.009(1)(d), FAC.	Yes

General Requirements for Office Surgery

9. Compliance with pre-operative Evaluation [64B8-9.009(2)(a) FAC] <i>Immediate pre-op eval not timed.</i>	Yes
9a. The surgeon(s) examined the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed <i>Immediate pre-op eval form not timed.</i>	Yes
9b. The surgeon(s) delegated the preoperative heart lung evaluation to a qualified anesthesia provider within the scope of the provider's practice and, if applicable, protocol.	Yes
10. Compliance with Patient/Procedures Records [64B8-9.009(2)(a) FAC]	Yes
11. Compliance with Informed Consent [64B8-9.009(2)(a), FAC] <i>Anesthesia consent form does not provide a choice of anesthesia provider.</i>	No
12. Surgical Logs contain confidential patient identifier, time of arrival in the operating suite, documentation of completion of the medical clearance as performed by the anesthesiologist or the operating physician, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, and any adverse incidents [64B8-9.009(2)(c), FAC] <i>Some log sheets identified that were incomplete. Adverse incident not specified on confidential patient identifier #'s 136872, 90907, 48603</i>	No
12a. The surgeon(s) completed Level II, Level III or Liposuction over 1,000cc procedures	Yes
12b. Surgical Logs are maintained for six years after last patient contact	Yes

Office Surgery Center

Eres Plastic Surgery

Insp # 281

File # 420

13. Compliance with liposuction procedures[64B8-9.009(2)(d), FAC]	Yes
13a. The surgeon(s) removed no more than 4,000 cc of fat	Yes
13b. The surgeon(s) injected no more than 50mg/kg of Lidocaine for tumescent liposuction	Yes
14. Compliance with Elective Cosmetic and Plastic Surgery Procedures[64B8- 9.009(2)(f), FAC]	Yes
14a. Surgery was completed in under 8 hrs.	Yes
14b. Patients were discharged within 24 hrs.	Yes
14c. If Patients time in office exceed 23 hrs. 59 minutes patient was transferred to a hospital.	N/A
15. Compliance with overnight stays except for elective cosmetic and plastic surgery[64B8-9.009(2)(f), FAC]	N/A
15a. Only elective cosmetic and plastic surgery patients stayed past midnight	N/A
15b. Overnight stays were limited to the physician's office <i>No overnight stays have done at this facility.</i>	N/A
16. Compliance with overnight stays in relation to any surgical procedure[64B8-9.009(2)(h), FAC]	N/A
16a. Two monitors were present (one monitor was ACLS certified)	N/A
16b. Monitor to patient ratio was kept at 1 monitor to 2 patients	Yes
16c. Once physician signed a timed and dated discharge order, single monitoring began by a ACLS certified monitor	Yes
16d. The surgeon(s) was reachable by telephone and available to return to the office within 15 minutes	Yes
17. Compliance with post-operative care[64B8-9.009(2)(h), FAC]	Yes
18. Compliance with risk management program[64B8-9.009(2)(i), FAC]	Yes
18a. Risk Management program includes the identification, investigation, and analysis of the frequency and causes of adverse incidents to patients	Yes
18b. Risk Management program includes the identification of trends or patterns of incidents	Yes
18c. Risk Management program includes the development of appropriate measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients	Yes
18d. Risk Management program includes the documentation of these functions and periodic review no less than quarterly of such information by the surgeon	Yes
19. Compliance with adverse incident reporting[64B8-9.009(2)(k), FAC] [64B8-9.001, FAC] [458.351 (4), FS]	Yes

Requirements for Level I (Liposuction) Office Surgery

20. Compliance with Training Requirements[64B8-9.009(3)(b)1, FAC]	Yes
21. Compliance with Equipment and Supplies Required[64B8-9.009(3)(b)2, FAC]	Yes
21a. Office has intravenous access supplies, oxygen, oral airways, and a positive pressure ventilation device	Yes
21b. Office stores the following medications at manufacturer's recommendation: Atropine 3 mg; Diphenhydramine 50 mg; Epinephrine 1 mg in 10 ml; Epinephrine 1 mg in 1 ml vial, 3 vials total; and Hydrocortisone 100 mg	Yes

Requirements for Level II Office Surgery

22. The surgeon(s) have Transfer Agreements or Hospital Staff Privileges for a licensed hospital within reasonable proximity (30 mins.) [64B8-9.009(4)(b)1, FAC]	Yes
23. Compliance with Training Requirements[64B8-9.009(4)(b)2, FAC]	Yes
24. At least one assistant is certified with Basic Life Support Certification[64B8-9.009(4)(b)2, FAC]	Yes
25. The surgeon(s) are currently certified with Advanced Cardiac Life Support Certification[64B8-9.009(4)(b)2, FAC]	Yes
26. The office has the following equipment/supplies: a Benzodiazepine must be present in the office.; Positive pressure ventilation device (e.g. Ambu) plus oxygen supply; End tidal CO2 detection device; Monitors for blood pressure/EKG/Oxygen saturation; Emergency intubation equipment, which shall at a minimum include suction devices, endotracheal tubes, laryngoscopes, oropharyngeal airways, nasopharyngeal airways and bag valve mask apparatus that are patient-size specific; Defibrillator with defibrillator pads or defibrillator gel, or an Automated External Defibrillator unit (AED); Sufficient back up power is required to allow the physician to safely terminate the procedure and to allow the patient to emerge from the anesthetic, all without compromising the sterility of the procedure or the environment of care; Sterilization equipment and IV solution and IV equipment. [64B8-9.009(4)(b)3, FAC]	Yes
27. Crash cart contains: Adenosine 18 mg; Albuterol 2.5 mg with small volume nebulizer; Amiodarone 300 mg; Atropine 3 mg; Calcium chloride 1 gram; Dextrose 50%; 50 ml; Diphenhydramine 50 mg; Dopamine 200 mg minimum; Epinephrine 1 mg in 10 ml; Epinephrine 1 mg in 1 ml vial, 3 vials total; Flumazenil 1 mg; Furosemide 40 mg; Hydrocortisone 100 mg; Lidocaine appropriate for cardiac administration 100 mg; Magnesium sulfate 2 grams; Naloxone 1.2 mg; A beta blocker class drug; Sodium bicarbonate 50 mEq/50 ml; Paralytic agent that is appropriate for use in rapid sequence intubation; A calcium channel blocker class drug; and, Intralipid 20% 500 ml solution (only if non-neuraxial regional blocks are performed). [64B8-9.009(4)(b)3a, FAC]	Yes
28. Compliance with Anesthesia Provider[64B8-9.009(4)(b)4, FAC]	Yes
29. Compliance with Additional Assistance[64B8-9.009(4)(b)4, FAC]	Yes

Requirements for Level III (Include the requirement for level II Office surgery as well as the requirements outlined)

30. Compliance with the American Society of Anesthesiologist's Classifications for appropriate candidates for level III office surgery[64B8-9.009(6)(a)2, FAC]	Yes
31. Complies with Additional Training Requirements[64B8-9.009(6)(b)1, FAC]	Yes
32. Emergency policies and procedures are periodically reviewed, updated, and posted in a conspicuous location. [64B8-9.009(6)(b)2, FAC]	Yes

Office Surgery Center
Eres Plastic Surgery

Insp # 281

File # 420

32a. Emergency policies and procedures cover the following: a. Airway Blockage (foreign body obstruction); b. Allergic Reactions; c. Bradycardia; d. Bronchospasm; e. Cardiac Arrest; f. Chest Pain; g. Hypoglycemia; h. Hypotension; i. Hypoventilation; j. Laryngospasm; k. Local Anesthetic Toxicity Reaction; and, l. Malignant Hyperthermia.	Yes
33. Office has the following equipment/supplies: at least 720 mg of dantrolene on site (if halogenated anesthetics or succinylcholine are utilized); must be comparable to a free standing ambulatory surgical center, including, but not limited to, recovery capability, and must have provisions for proper recordkeeping; Blood pressure monitoring equipment; EKG; end tidal CO2 monitor; pulse oximeter, emergency intubation equipment and a temperature monitoring device; and Table capable of trendelenburg and other positions necessary to facilitate the surgical procedure [64B8-9.009(6)(b)3, FAC]	Yes
34. Complies with Anesthesia Provider[64B8-9.009(6)(b)4, FAC]	Yes
35. Complies with Additional Assistance of Other Personnel Required[64B8-9.009(6)(b)4, FAC]	Yes

Remarks:

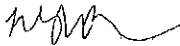
Per Chief Operating Officer Giannina Sopo, Dr Amaryllis Pascual has not performed surgeries since 5/10/17.

Operative note missing from charts 174841, 138844 and 255 found at time of inspection and added to charts. 144582 also missing operative report.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

TAYLOR, NICOLE



Date: 7/11/2017

Representative:

Giannina F. Sopo



Date: 7/11/2017

Lagunzia

JOLIE PLASTIC SURGERY
8506 SW 8TH ST
MIAMI, FL 33144

08/16/2017 1,500.00
ID: 420 Type: F
BT: 3003052
RT: 917007681

July 31, 2017

Dept of Health
Board of Medicine
4052 Bald Cypress Way, BIN #C03
Tallahassee, FL 32399
Office Surgery Department

RE: PLAN OF CORRECTION:

Jolie Plastic Surgery OSR# 350

Location Address: 8506 SW 8 St, Miami, FL, 33144

Date of Inspection: 07-11-2017

Registered Physicians: Dr. Daniel Calva, ME 120264; Dr. Salas ME 108242; Dr. Jonathan Fischer ME96746 & Dr. Camille Chavez, ME 68329; Dr. Ravinder S. Jarial, ME 9321; Dr. Amaryllis Pascual ME 94686; Eric Valladares ME91049; Arnaldo Valls ME 82727 Carlos Verdeza ME97208

Conducted by: Nicole Taylor, RN

As of July 12, 2017, the office surgery center has begun implementing the following deficiencies:

Gigi Sopo and risk manager shall be responsible for the corrective action and ongoing compliance.


The administrative staff, RN, surgeons and anesthesia personnel have been in serviced on July 14, 2017 for the following deficiencies and shall maintain compliance with Chapter 458.309 Rule 64B8-9.0091, F.A.C.

1. Tag # 9 Compliance with Informed consent:

Gigi Sopo met with his administrative staff and discussed the Quality Assurance issues discovered by the lack of documentation (choice of anesthesia provider) on the informed consents during the inspection have been corrected; Staff has been made use the updated anesthesia consent form which includes the verbiage "choice of anesthesia provider". It will be the responsibilities of Gigi Sopo and risk manager in maintaining the ongoing compliance.

2. Tag #12 Surgical log: The QA issues discovered during the inspection have been corrected. Risk manager conducted a meeting with the clinical staff on how to properly document the surgical log. The responsible staff understands the importance of completing each surgical log in its entirety. It will be the responsibilities of Risk Manager in maintaining the ongoing compliance.

I have read this Plan of Correction Report and affirm that the information given herein is true and correct to the best of my knowledge.


Emmanuel Pimentel
President

8-1-17
Date

2017 AUG 18 AM 10:01
BOARD OF MEDICINE

2017 AUG 15 PM 3:44
BOARD OF MEDICINE

1025



DEPARTMENT OF HEALTH
OFFICE SURGERY INSPECTION FORM
LEVEL II & III

4052 BALD CYPRESS WAY, BIN #C03
TALLAHASSEE, FLORIDA 32399-3253
INSPECTION AUTHORITY - CHAPTER 458.309, FLORIDA STATUTES;
RULE 64B8-9.0091, FLORIDA ADMINISTRATIVE CODE



NAME OF OFFICE SURGERY FACILITY QUEST Surgery CTR OSR 857				DATE OF INSPECTION 12-13-13			
STREET ADDRESS 1738 W 49TH ST				PHYSICIAN NAME (S) S. Bass ME 79410			
TELEPHONE 905-282-7690		COUNTY Miami-Dade		LICENSE NUMBERS R. Ghurani			
CITY Hialeah		STATE/ZIP FL 33012		E. Pelayo ME 94616		ME 89865	
Requirement for Physician Office Registration				Requirements for Level II Office Surgery			
1. The physician(s) is registered to perform office-based surgery with the Board of Medicine (64B8-9.0091)(1)				22. Transfer Agreement Required in Hospital Staff Privileges (64B8-9.009(4)(b), FAC)			
2. The physician(s) office is not accredited with a national accrediting organization or Board approved organization				23. Compliance with Training Requirements (64B8-9.009(4)(b)2, FAC)			
3. The physician(s) performs surgery as defined in the Board (64B8-9.009(1)(c), FAC)				24. Compliance with Basic Life Support Certification (64B8-9.009(4)(b)2, FAC)			
4. The surgeon(s) is an active licensed physician(s) in the State of Florida (64B8-9.009(1)(b), FAC)				25. Compliance with Advanced Cardiac Life Support Certification (64B8-9.009(4)(b)2, FAC)			
5. The equipment meets the current performance standards (64B8-9.009(1)(c), FAC)				26. Compliance with Equipment and Supplies Required (64B8-9.009(4)(b)3, FAC)			
6a. The surgery is being performed outside a hospital, ambulatory surgical center, abortion clinic or other medical facility licensed by the Department of Health or the Agency for Health Care Administration (64B8-9.009(1)(c), FAC)				27. Compliance with Crash Cart Resuscitative Medications (64B8-9.009(4)(b)3a, FAC)			
6b. The surgery is being performed pursuant to definition of office surgery as described in (64B8-9.009(1)(d))				28. Compliance with Anesthesia Provider (64B8-9.009(4)(b)4, FAC)			
General Requirements for Office Surgery				29. Compliance with Additional Assistance (64B8-9.009(4)(b)4, FAC)			
7. Compliance with pre-operative Evaluation (64B8-9.009(2)(a), FAC)				30. Compliance with Recovery Monitoring (64B8-9.009(4)(b)4, FAC)			
8. Compliance with Patient/Procedures Records (64B8-9.009(2)(a), FAC)				Requirements for Level III (Include the requirement for level II Office surgery as well as the requirements outlined)			
9. Compliance with Informed Consent (64B8-9.009(2)(a), FAC)				31. Compliance with the American Society of Anesthesiologist's Classifications for appropriate candidates for level III office surgery (64B8-9.009(6)(a)2, FAC)			
10. Compliance with Surgical Logs (64B8-9.009(2)(c), FAC)				32. Complies with Additional Training Requirements (64B8-9.009(6)(b)1, FAC)			
11. Compliance with Liposuction procedures (64B8-9.009(2)(d), FAC)				33. Complies with Emergency Procedures (64B8-9.009(6)(b)2, FAC)			
12. Compliance with Liposuction combination procedures (64B8-9.009(2)(e), FAC)				34. Complies with Additional Equipment and Supplies (64B8-9.009(6)(b)3, FAC)			
13. Compliance with Elective Cosmetic and Plastic Surgery Procedures (64B8-9.009(2)(f), FAC)				35. Complies with Anesthesia Provider (64B8-9.009(6)(b)4, FAC)			
14. Compliance with overnight stays except for elective cosmetic and plastic surgery (64B8-9.009(2)(f), FAC)				36. Complies with Additional Assistance of Other Personnel Required (64B8-9.009(6)(b)4, FAC)			
15. Compliance with overnight stays in relation to any surgical procedure (64B8-9.009(2)(f), FAC)				Miscellaneous (Please Specify)			
16. Compliance with post-operative care (64B8-9.009(2)(h), FAC)				Dr. Hassan ME 78230			
17. Compliance with anesthetic monitoring (64B8-9.009(2)(g), FAC)				Dr. Salas ME 108242			
18. Compliance with policy and procedures manual (64B8-9.009(2)(i), FAC)				Dr. Rodriguez ME 102571			
19. Compliance with risk management program (64B8-9.009(2)(j), FAC)							
20. Compliance with adverse incident reporting (64B8-9.009(2)(k), FAC)							
21. Compliance with signage (64B8-9.009(2)(l), FAC)							

Comments: Dr. Pelayo Does Level I - SX - Registered 2/12/12, but no transfer Agreement; privileges e Kendall Regional for internal medicine. Dr. Bass privileges e Metropolitan in General sx e plastic sx privileges; not board center eligible. 8) Many forms in the medical record shows from different surgical ctrs. i.e: consents, pre op, intra op + post op forms. 10 West Sx ctr D.B.A. "Vanity". but forms state "Vanades or West Dade". only 1 set of

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Signature of Responsible Party

Date

Investigator

Date

1002

Office Surgery Inspection Form Continued from Page 1.
Additional Findings:

Date: 12-13-13

OSR #: 857

minutes since Dec. 2012. RM only comes in once a year prior to inspection. 1-medication Dopamine is on back-order. (see proof from McKesson). Registration of staff does not match what the state has on file. There are quite a few anesthesia providers, RN, MA's, ST on site. Autoclave log documentation did not reflect each autoclave; peel packs were folded in the larger pack. Writing on the peel packs is in the wrong place. no documentation for the weekly cleaning of the (2) autoclaves.

Level I Surgery - No time outs being performed. Fat transfers are being performed. 1M-50mg Benadryl is administered along with 1g of an antibiotic + 1mg of Lorazepam-PO. Cases average 1600 - 3800 ml per procedure. These are findings from today 12-13-13.

PCC given. 64B8-9.007; 64B8-9.0091 rules were given to the facility.



Signature of Facility:

12/13/13

Date:

 BENEDETTI, URM

Signature of Inspector:

12/13/13

Date:

2062

Dr. Pelayo
Approved for Level 1
on Dec. 19, 12.

No Transfer Agreement
or
Hospital privileges for
LIPO

? how he was approved
or even after 3/13
ruling?

Also gives 1m Benadryl
50mg + 1g of Antibiotic
along w PO sedation -

Long cases 3 hrs. + up to
3800ml SNF.

IQUEST SURGERY CENTER, D.B.A. VANITY COSMETIC SURGERY
1738 W 49TH ST
HIALEAH, FL 33012

January 8, 2014

Dept of Health
Board of Medicine
4052 Bald Cypress Way, BIN #C03
Tallahassee, FL 32399
Office Surgery Department

Page | 1

MEDICINE BOARD
14 JAN 16 PM 3:36

RE: CORRECTIVE ACTION PLAN

Iquest Surgery Center, DBA Vanity Cosmetic Surgery OSR# 857

Location Address: 1738 W 49 St, Hialeah, FL, 33012

Date of Inspection: 12-13-2013

Registered Physicians: Dr. Rami Ghurani, ME 89865; Dr. Salas ME 108242; Dr. Anthony Hasan, ME 78230; Siddharth Bass, MD ME 79410; Enrique Pelayo ME 94616;

Conducted by: Deanna K Pfoff, RN, LHCM

As of December 16, 2013, the office surgery center has begun implementing the following deficiencies:

Dr. Ismael Labrador, Administrator/Medical Director of Iquest Surgery Center, DBA Vanity Cosmetic Surgery is responsible for the corrective action and ongoing compliance.

The administrative staff, RN, surgeons and anesthesia personnel have been in serviced on December 22, 2013 for the following deficiencies and shall maintain compliance with Chapter 458.309 Rule 64B8-9.0091, F.A.C.

1. Attached to this plan of correction is the updated Application with the correct name of the Business.
2. Tag # 8 Compliance with Patient /Procedures records;
 - a. Dr. Ismael Labrador met with his administrative staff and discussed the Quality Assurance issues discovered during the inspection have been corrected; the administrative staff will be proactive in obtaining the correct medical records form for each center. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.
3. Tag # 19 Compliance with Risk Management: At the present time the organization chooses to perform their risk management minutes on a quarterly basis. It will be the responsibility of Dr. Ismael Labrador to ensure compliance by conducting and documenting the quarterly Risk Management minutes.
4. Tag#23 Hospital Privileges Dr. Bass ME 79410 the general surgeon does not have a board in Plastics, however attached are his training credentials for plastics and/or cosmetic procedures. Dr. Enrique Pelayo was not able to obtain privileges for Liposuction at Kendall hospital or any hospital in the vicinity. Therefore, Dr. Enrique Pelayo has been made aware that he cannot perform liposuction procedures until he

IQUEST SURGERY CENTER, D.B.A. VANITY COSMETIC SURGERY
1738 W 49TH ST
HIALEAH, FL 33012

obtains the appropriate privileges. It will be the responsibilities of Ismael Labrador, Administrator. See attached documents

5. Miscellaneous;

- a. Dr. Ismael Labrador met with the responsible staff in charge of cleaning of instrumentation and discussed the Quality Assurance issues discovered during the inspection; the staff will be proactive in documenting the correct information in the autoclave logs; proper packing techniques and documentation on the peel packs and properly document the weekly cleaning logs of the (2) autoclaves. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.
- b. Dr. Ismael Labrador met with the responsible staff in charge of timeouts and discussed the Quality Assurance issues discovered during the inspection; the staff has been in serviced to ensure Timeouts are being performed for all levels of Surgery.

Page | 2

6. All registered CRNAs have a signed protocol with the surgeons. The CRNAs have submitted to the Dept of Health their signed Protocol detailing their supervising physician. It will be the responsibilities of Ismael Labrador, MD, administrator in maintaining the ongoing compliance.

On the day of the inspection we clarified with the inspector our current staff. We are notifying the State that based on our database the following registered physicians are No Longer working at our facility Raul Rodriguez.

7. We are notifying the State that based on our database the following registered physicians and clinical staff that are currently working at our facility:

Physicians: Anthony Hasan, Rafael Salas, Rami Ghurani, and Siddarth Bass
CRNA/ARNPs: Jason Vera, Sergio Hernandez, Gabriel Dietsch, Demarko Bazan, , Christopher Jorge, Alexandra Cortes, Mario de la Portilla, Lourdes Dieguez, Richard Lauriello, Seng Fook Lam, Jesus del Risco, Justin Jimenez, Miguel Vasallo, Carolina Wilson, Frankie Lima, , Monica Gross Ramos, Susana Airala, Roberto Fernandez, Alex Quinones, Richard Eckert, MD Anesthesia: Jorge Melgen, Eduardo Lorenzo, Carlos Lazalle, Stephane Omezuine, Osmar Creagh.

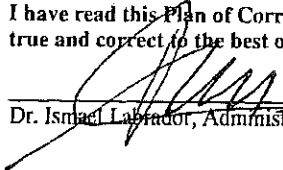
RN: Massiel Ruiz, Yuneidys Aguilar, Jessica D. Collazo

Circulators/Medical Assistants: Betsy Reyes, Yunia Calero, Graciela Rodriguez, Adiana Morell, Laura Muriedas.

Surgical Assistants/Technologist: Lester Trastoy, Jorge Jova, Marleivys Romero, Mitdael Moreno, Mario Ledesma, Orlando Cardelles, Alberto Toledo.

QUEST SURGERY CENTER, D.B.A. VANITY COSMETIC SURGERY
1738 W 49TH ST
HIALEAH, FL 33012

I have read this Plan of Correction Report and affirm that the information given herein is true and correct to the best of my knowledge.


Dr. Ismael Labrador, Administrator

01-08/2014
Date

Page | 3

Plan of Correction was prepared by Dr. Laura A. Leyva, MBA, HSA, LHCRM, Physician Consultants, Inc.
email:Physicianconsult@aol.com

4052 BALD CYPRESS WAY, BIN #C03
TALLAHASSEE, FLORIDA 32399-3253
INSPECTION AUTHORITY – CHAPTER 458.309, FLORIDA STATUTES;
RULE 64B8-9.0091, FLORIDA ADMINISTRATIVE CODE

DSR 857

Florida HEALTH

NAME OF OFFICE SURGERY FACILITY				DATE OF INSPECTION		
STREET ADDRESS				PHYSICIAN NAME(S)		
TELEPHONE				LICENSE NUMBERS		
CITY				STATE/ZIP		
REQUEST SURGERY CENTER				12-30-14		
1738 W 49th ST, HIALEAH				JAMES McADOO		
305 282-7690				SINGH BASS		
MIAMI-DADE				ME 79410		
HIALEAH				FL 33012		
				L LORENTS, ORLANDO		
				ME 99849		
Requirement for Physician Office Registration				YES	NO	NA
1. The physician(s) is registered to perform office-based surgery with the Board of Medicine[64B8-9.009(1)(f)]				✓		
2. The physician(s) office is not accredited with a national accrediting organization or Board approved organization				✓		
3. The physician(s) performs surgery as defined in the Board [64B8-9.009(1)(a), FAC]				✓		
4. The surgeon(s) is an active licensed physician(s) in the State of Florida[64B8-9.009(1)(b), FAC]				✓		
5. The equipment meets the current performance standards[64B8-9.009(1)(c), FAC]				✓		
6a. The surgery is being performed outside a hospital, ambulatory surgical center, abortion clinic or other medical facility licensed by the Department of Health or the Agency for Health Care Administration[64B8-9.009(1)(d), FAC]				✓		
6b. The surgery is being performed pursuant to definition of office surgery as described in 64B8-9.009(1)(d)				✓		
General Requirements for Office Surgery						
7. Compliance with pre-operative Evaluation[64B8-9.009(2)(a) FAC]				✓		
8. Compliance with Patient/Procedures Records[64B8-9.009(2)(a) FAC]				✓*		
9. Compliance with Informed Consent[64B8-9.009(2)(a), FAC]				✓	✓	
10. Compliance with Surgical Logs[64B8-9.009(2)(c), FAC]				✓*		
11. Compliance with liposuction procedures[64B8-9.009(2)(d), FAC]				✓		
12. Compliance with liposuction combination procedures[64B8-9.009(2)(e), FAC]				✓		
13. Compliance with Elective Cosmetic and Plastic Surgery Procedures[64B8-9.009(2)(f), FAC]				✓		
14. Compliance with overnight stays except for elective cosmetic and plastic surgery[64B8-9.009(2)(f), FAC]						✓
15. Compliance with overnight stays in relation to any surgical procedure[64B8-9.009(2)(h), FAC]						✓
16. Compliance with post-operative care[64B8-9.009(2)(h), FAC]				✓		
17. Compliance with anesthetic monitoring[64B8-9.009(2)(g), FAC]				✓*		
18. Compliance with policy and procedures manual[64B8-9.009(2)(i), FAC]				✓		
19. Compliance with risk management program[64B8-9.009(2)(j), FAC]					✓	
20. Compliance with adverse incident reporting[64B8-9.009(2)(k), FAC]					✓	
21. Compliance with signage[64B8-9.009(2)(l), FAC]				✓		
Requirements for Level II Office Surgery				YES	NO	NA
22. Transfer Agreement Required or Hospital Staff Privileges [64B8-9.009(4)(b), FAC]				✓		
23. Compliance with Training Requirements[64B8-9.009(4)(b)2, FAC]				✓		
24. Compliance with Basic Life Support Certification[64B8-9.009(4)(b)2, FAC]				✓		
25. Compliance with Advanced Cardiac Life Support Certification[64B8-9.009(4)(b)2, FAC]				✓		
26. Compliance with Equipment and Supplies Required[64B8-9.009(4)(b)3, FAC]				✓		
27. Compliance with Crash Cart Resuscitative Medications[64B8-9.009(4)(b)3a, FAC]				✓		
28. Compliance with Anesthesia Provider[64B8-9.009(4)(b)4, FAC]				✓		
29. Compliance with Additional Assistance[64B8-9.009(4)(b)4, FAC]				✓		
30. Compliance with Recovery Monitoring[64B8-9.009(4)(b)4, FAC]				✓		
Requirements for Level III (Include the requirement for level II Office surgery as well as the requirements outlined)						
31. Compliance with the American Society of Anesthesiologist's Classifications for appropriate candidates for level III office surgery[64B8-9.009(6)(a)2, FAC]				✓*		
32. Complies with Additional Training Requirements[64B8-9.009(6)(b)1, FAC]				✓		
33. Complies with Emergency Procedures[64B8-9.009(6)(b)2, FAC]				✓*		OK RS
34. Complies with Additional Equipment and Supplies[64B8-9.009(6)(b)3, FAC]				✓		
35. Complies with Anesthesia Provider[64B8-9.009(6)(b)4, FAC]				✓		
36. Complies with Additional Assistance of Other Personnel Required[64B8-9.009(6)(b)4, FAC]				✓		
Miscellaneous (Please Specify)						
XCRNAS NEED TO HAVE BOTH BDN + BOM PROTOCOLS AT THIS ADDRESS WITH PHYSICIANS WORKING HERE.						

Comments: #8 MISSING ANESTHESIA TIME OUT ALL CHARTS, SOME TIME OUTS PERFORMED ONLY OUTSIDE OF THE OR, #9 CONSENTS MUST BE TIMED WHEN SIGNED DAY OF SURGERY TO INDICATE PREANESTHESIA; CONSENTS MUST LIST PROCEDURE AND SHOULD NOT BE ABBREVIATED. MISSING SPECIFIC TYPE OF ANESTHESIA PROVIDER ON 4/9 CHARTS. #10 NAMES LISTED ON SOME LOGS - MUST BE CONFIDENTIAL PATIENT ID ONLY. #17 1/9 CHARTS MISSING - QUANTITATIVE ET_{CO2} ON LMA GENERAL CASE CRNA Dietzen #19 Policy states Quarterly MEETINGS BUT NONE DOCUMENTED FOR

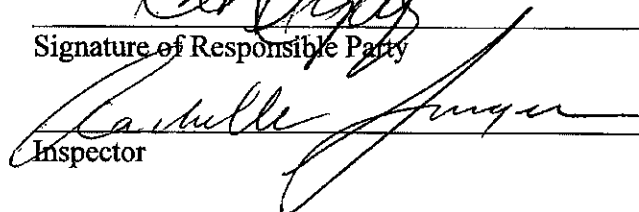
I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Office Surgery Inspection Form Date 12-30-14 Page Number 2 of 2
Facility Name QUEST SURGERY CENTER OSR # 857

PAST 2 YEARLY INSPECTIONS. #20 ADVERSE INCIDENT ON
10/30/14 NOT REPORTED UNTIL 12/29/14. #31, 1/9 CHARTS
MISSING PREOP EKG FOR PATIENT 740 ASATT. #33
~~A20 EMERGENCY DRILLS FOR DR. BASS IN PAST YEAR~~ ERROR
RS


Signature of Responsible Party

12/30/14
Date


Inspector

12-30-14
Date

IQUEST SURGERY CENTER, D.B.A. VANITY COSMETIC SURGERY

1738 W 49TH ST
HIALEAH, FL 33012

January 29, 2015

Dept of Health
Board of Medicine
4052 Bald Cypress Way, BIN #C03
Tallahassee, FL 32399
Office Surgery Department

Page | 1

15 FEB -2 PM 2:14
MEDICINE BOARD

RE: CORRECTIVE ACTION PLAN

Iquest Surgery Center, DBA Vanity Cosmetic Surgery OSR# 857

Location Address: 1738 W 49 St, Hialeah, FL, 33012

Date of Inspection: 12-13-2013

Registered Physicians: Siddharth Bass, MD ME 79410; James McAdoo OS 11955; Orlando LLorente, ME 99849

Conducted by: Rachelle Springer, RN, LHCRM

As of January 2, 2015, the office surgery center has begun implementing the following deficiencies:

Dr. Ismael Labrador, Administrator/Medical Director of Iquest Surgery Center, DBA Vanity Cosmetic Surgery is responsible for the corrective action and ongoing compliance.

The administrative staff, RN, surgeons and anesthesia personnel have been in serviced for the following deficiencies and shall maintain compliance with Chapter 458.309 Rule 64B8-9.0091, F.A.C.

1. Tag # 8 & 9 Compliance with Patient /Procedures records and Compliance with Informed Consent;

- a. Tag8-Dr. Ismael Labrador met with his administrative staff and discussed the Quality Assurance issues discovered during the inspection that has been corrected; the facility was given a new time out form to ensure anesthesia time outs are performed in the OR. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.
- b. Tag 9- Dr. Ismael Labrador met with his administrative staff and discussed the Quality Assurance issues discovered during the inspection that has been corrected; consent will be timed when signed on the day of surgery to indicate pre-anesthesia and the consent shall list the procedures without abbreviations. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.

2. Tag # 10 Compliance with Surgical Logs

Dr. Ismael Labrador met with his administrative staff and discussed the Quality Assurance issues discovered during the inspection that has been corrected; the surgical log shall contain the confidential patient IDs only. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.

15 JAN -2 PM 1:48
MEDICINE BOARD

IQUEST SURGERY CENTER, D.B.A. VANITY COSMETIC SURGERY
1738 W 49TH ST
HIALEAH, FL 33012

3. Tag #17 Compliance with Anesthetic monitoring: Dr. Ismael Labrador met with his CRNA staff and discussed the Quality Assurance issues discovered during the inspection that has been corrected; the topic of quantitative ETCO2 on LMA on general cases was discussed and understood by all CRNAs. It will be the responsibilities of Dr. Ismael Labrador, administrator in maintaining the ongoing compliance.
4. Tag # 19 Compliance with Risk Management: At the present time the organization chooses to perform their risk management minutes on a quarterly basis. It will be the responsibility of Dr. Ismael Labrador to ensure compliance by conducting and documenting the quarterly Risk Management minutes.
5. Tag#20 Compliance with Adverse Incident reporting. It will be the responsibilities of Ismael Labrador, Administrator, to ensure all incidents are reported on a timely matter. Dr Orlando Llorete was informed of the rule by the risk manager.
6. All registered CRNAs have a signed protocol with the surgeons. The CRNAs have submitted to the Dept of Health their signed Protocol detailing their supervising physician. It will be the responsibilities of Ismael Labrador, MD, administrator in maintaining the ongoing compliance.

Page | 2

On the day of the inspection we clarified with the inspector our current staff. We are notifying the State that based on our database the following registered physicians are No Longer working at our facility Rafael Salas, Rami Ghurani Anthony Hasan

7. We are notifying the State that based on our database the following registered physicians and clinical staff that are currently working at our facility:

Physicians: James McAdoo, Orlando Llorete and Siddarth Bass

CRNA/ARNPs: Jason Vera, Sergio Hernandez, Gabriel Dietsch, Demarko Bazan, ,
~~Cristopher Jorge, Alexandra Cortes, Mario de la Portilla, Lourdes Dieguez, Richard~~
~~Lauriello, Seng Fook Lam, Jesus del Risco, Justin Jimenez, Miguel Vasallo, Carolina~~
~~Wilson, Frankie Lima, , Monica Gross Ramos, Susana Airala, Roberto Fernandez, Alex~~
~~Quinones, Richard Eckert, MD Anesthesia: Jorge Melgen, Eduardo Lorenzo, Carlos~~
~~Lazalle, Stephane Otmezguine, Osmar Creagh.~~

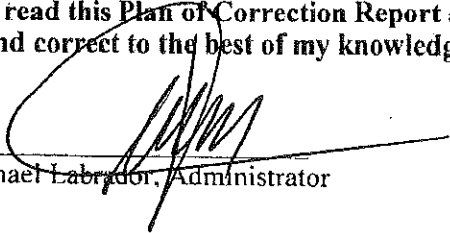
RN: Massiel Ruiz, Yuneidys Aguilar, Jessica D. Collazo

Circulators/Medical Assistants: Betsy Reyes, Yunia Calero, Graciela Rodriguez,
~~Adiana Morell, Laura Muriedas.~~

Surgical Assistants/Technologist: Lester Trastoy, Jorge Iova, Marleivys Romero,
~~Mitdael Moreno, Mario Ledesma, Orlando Cardelles, Alberto Toledo.~~

IQUEST SURGERY CENTER, D.B.A. VANITY COSMETIC SURGERY
1738 W 49TH ST
HIALEAH, FL 33012

I have read this Plan of Correction Report and affirm that the information given herein is true and correct to the best of my knowledge.


Dr. Ismael Labrador, Administrator


Date

Page | 3

Plan of Correction was prepared by Dr. Laura A. Leyva, MBA, HSA, RM,
LAL HealthCare and Risk Management Services, P.A. email:Physicianconsult@aol.com



DEPARTMENT OF HEALTH
OFFICE SURGERY INSPECTION FORM
LEVEL II & III

4052 BALD CYPRESS WAY, BIN #C03
TALLAHASSEE, FLORIDA 32399-3253
INSPECTION AUTHORITY - CHAPTER 458.309, FLORIDA STATUTES
RULE 64B8-9.0091, FLORIDA ADMINISTRATIVE CODE

MEDICINE BOARD

16 FEB 23 PM 2:58

FLORIDA
HEALTH

ENCORE PLASTIC SURGERY OR 857

NAME OF OFFICE SURGERY FACILITY (QUEST SURGERY CENTER DBA VARIETY) NAME CHANGED			DATE OF INSPECTION 1-27-16				
STREET ADDRESS 1738 W 49th ST			PHYSICIAN NAME(S) MIC ADDO, JAMES				
TELEPHONE 305-282-7690	COUNTY MIAMI-DADE	FLORIDA	LICENSE NUMBERS 11955				
CITY MIAMI	STATE/ZIP FL 33012	FLORIDA	79410				
Requirement for Physician Office Registration			Requirements for Level II Office Surgery				
1. The physician(s) is registered to perform office-based surgery with the Board of Medicine[64B8-9.0091(1)]	YES	NO	NA	22. Transfer Agreement Required or Hospital Staff Privileges [64B8-9.009(4)(b), FAC]	YES	NO	NA
2. The physician(s) office is not accredited with a national accrediting organization or Board approved organization	✓			23. Compliance with Training Requirements[64B8-9.009(4)(b)2, FAC]	✓		
3. The physician(s) performs surgery as defined in the Board [64B8-9.009(1)(a), FAC]	✓			24. Compliance with Basic Life Support Certification[64B8-9.009(4)(b)2, FAC]	✓		
4. The surgeon(s) is an active licensed physician(s) in the State of Florida[64B8-9.009(1)(b), FAC]	✓			25. Compliance with Advanced Cardiac Life Support Certification[64B8-9.009(4)(b)2, FAC]	✓		
5. The equipment meets the current performance standards[64B8-9.009(1)(c), FAC]		✓		26. Compliance with Equipment and Supplies Required[64B8-9.009(4)(b)3, FAC]		✓	
6a. The surgery is being performed outside a hospital, ambulatory surgical center, abortion clinic or other medical facility licensed by the Department of Health or the Agency for Health Care Administration[64B8-9.009(1)(d), FAC]	✓			27. Compliance with Crash Cart Resuscitative Medications[64B8-9.009(4)(b)3a, FAC]	✓		
6b. The surgery is being performed pursuant to definition of office surgery as described in 64B8-9.009(1)(d)	✓			28. Compliance with Anesthesia Provider[64B8-9.009(4)(b)4, FAC]	✓		
General Requirements for Office Surgery			29. Compliance with Additional Assistance[64B8-9.009(4)(b)4, FAC]				
7. Compliance with pre-operative Evaluation[64B8-9.009(2)(a) FAC]		✓		30. Compliance with Recovery Monitoring[64B8-9.009(4)(b)4, FAC]	✓		
8. Compliance with Patient/Procedures Records[64B8-9.009(2)(a) FAC]	✓			Requirements for Level III (Include the requirement for level II Office surgery as well as the requirements outlined)			
9. Compliance with Informed Consent[64B8-9.009(2)(a), FAC]		✓		31. Compliance with the American Society of Anesthesiologist's Classifications for appropriate candidates for level III office surgery[64B8-9.009(6)(a)2, FAC]		✓	
10. Compliance with Surgical Logs[64B8-9.009(2)(c), FAC]		✓		32. Complies with Additional Training Requirements[64B8-9.009(6)(b)1, FAC]	✓	✓	
11. Compliance with liposuction procedures[64B8-9.009(2)(d), FAC]	✓			33. Complies with Emergency Procedures[64B8-9.009(6)(b)2, FAC]		✓	
12. Compliance with liposuction combination procedures[64B8-9.009(2)(e), FAC]	✓			34. Complies with Additional Equipment and Supplies[64B8-9.009(6)(b)3, FAC]	✓		
13. Compliance with Elective Cosmetic and Plastic Surgery Procedures[64B8-9.009(2)(f), FAC]	✓			35. Complies with Anesthesia Provider[64B8-9.009(6)(b)4, FAC]	✓		
14. Compliance with overnight stays except for elective cosmetic and plastic surgery[64B8-9.009(2)(f), FAC]			✓	36. Complies with Additional Assistance of Other Personnel Required[64B8-9.009(6)(b)4, FAC]	✓		
15. Compliance with overnight stays in relation to any surgical procedure[64B8-9.009(2)(h), FAC]			✓	Miscellaneous (Please Specify)			
16. Compliance with post-operative care[64B8-9.009(2)(h), FAC]	✓			MURPHY, OSAR 99126			
17. Compliance with anesthetic monitoring[64B8-9.009(2)(g), FAC]	✓						
18. Compliance with policy and procedures manual[64B8-9.009(2)(i), FAC]		✓					
19. Compliance with risk management program[64B8-9.009(2)(j), FAC]		✓					
20. Compliance with adverse incident reporting[64B8-9.009(2)(k), FAC]	✓						
21. Compliance with signage[64B8-9.009(2)(l), FAC]		✓					

Comments: #5 MISSING BIOMEDICAL INSPECTION MEDICATION REFRIGERATOR #7 5/9
CHARTS FILLED OUT BY MEDICAL ASSISTANT OR BLANK - IMMEDIATE PREOP
ASSESSMENT IS SURGEON'S RESPONSIBILITY TO PERFORM AND DOCUMENT. #8
119 CHARTS RECOVERY RECORD MISSING PULSE & OXYGENSATURATION.
#9 NEED TIME DAY OF SURGERY NEEDED TO LIST
PROCEDURES ON CONSENT AND SPECIFIC AREAS OF SURGERY - ESPECIALLY
LIPOSUCTION AND FAT TRANSFER. ANESTHESIA CONSENT MUST SPECIFY

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Signature of Responsible Party

Date

Investigator

Date

CRAA OR MD (1/9 CHARTS). 1/9 ANESTHESIA CONSENTS WITH SIGNIFICANT CROSSOUTS AND WRITE OVERS BY STAFF. NO INDICATION IF PATIENT SIGNED BEFORE OR AFTER.
#10 MISSING ADVERSE INCIDENT DOCUMENTATION ON LOG SINCE 6/15. #17 1/9 CHARTS FREITAS CRAA DOCUMENTED EKG, O₂ SATURATION, END TIDAL CO₂ AND TEMPERATURE ONLY EVERY 30 MINUTES DURING 2.5 HOUR GENERAL INTUBATION CASE. #18 NO QA OR QI POLICIES. #19 NO RISK MANAGEMENT PROGRAM OR MEETINGS. #21 NEED 64 BLS IN CONSENTS FOR DR. MCNOOD. #22 UNABLE TO PROVIDE DOCUMENTATION OF CURRENT PLASTIC SURGICAL PRIVILEGES FOR DR. OMULEPU. #26 UNABLE TO DEMONSTRATE BACKUP POWER FOR BOTH ORS - ONLY 1. BOTH IN SERVICE SIMULTANEOUSLY AT TIMES.
#31 2/9 CHARTS NO EKG FOR ASIA IF PATIENTS OVER 40. #33 DR BASS NO EMERGENCY DRILLS.

Signature of Responsible Party

Date

Inspector

Date

Encore Plastic Surgery (formerly Iquest) Medical Records Review 1-27-16 OSR 857

Medical Assistant documents all follow-up visits and MD signs off. No indication that MD is seeing the patients.

Patient ID 7063

Age 37

ASA II

Liposuction and abdominoplasty

3-17-15

General Anesthesia

Dr. Llorente

Consents signed day of surgery must be timed to indicate pre anesthesia. Consents missing specific anatomical areas for liposuction.

Patient ID 38727

Age 24

ASA I

Liposuction and abdominoplasty

6-26-15

General Anesthesia

Dr. Llorente

Consents signed day of surgery must be timed to indicate pre anesthesia. Consents missing specific anatomical areas for liposuction. Immediate preoperative assessment documented by medical assistant and signed by MD without indication that it was performed by the MD – heart and lungs “within normal limits” per medical assistant.

Patient ID 4085

Age 30

ASA I

Liposuction and augmentation mastopexy

2-10-15

General Anesthesia

Dr. Llorente

Consents signed day of surgery must be timed to indicate pre anesthesia. Consents missing specific anatomical areas for liposuction and procedure within the body of the consent. Anesthesia form difficult to read.

Patient ID 81083
Age 19 male
ASA II
Liposuction and abdominoplasty
12-19-15
General Anesthesia
Dr. Omulepu

Consents should have full name of surgeon, not just nickname. Consents missing specific anatomical areas for liposuction. CRNA performed the anesthesia but consent states MD. Chart refers to patient as she throughout and patient is a male. Surgeon classified patient as ASA III for a level III surgery. CRNA states ASA II.

Patient ID 42524
Age 35
ASA II
Breast augmentation
5-12-15
General Anesthesia
Dr. Omulepu

Consents should have full name of surgeon, not just nickname. Consents missing specific procedure within the body of the consent. Immediate preoperative assessment documented by medical assistant and signed by MD without indication that it was performed by the MD – heart and lungs “within normal limits” per medical assistant. Missing patient name and date on preanesthesia assessment.

Patient ID 41957
Age 47
ASA II
Liposuction and fat transfer
6-6-15
General Anesthesia – Freitas CRNA
Dr. Omulepu

Consents signed day of surgery must be timed to indicate pre anesthesia. Consents missing specific anatomical areas for liposuction and fat transfer. Missing EKG preop on ASA II age 47. Immediate preoperative assessment documented by medical assistant and signed by MD without indication that it was performed by the MD. Anesthesia record documents EKG, oxygen saturation, end tidal CO2 and temperature only every 30 minutes. Recovery record missing pulse, oxygen saturation, respirations and discharge time.

Patient ID 58100

Age 46

ASA II

Circumferential body lift

8-17-15

General Anesthesia

Dr. McAdoo

Anesthesia consent with multiple cross outs and write overs. No way to know if patient signed before or after modifications performed by staff. Consent missing verbiage for 64B15 as physician is an osteopath. Immediate preoperative assessment documented by medical assistant and signed by MD without indication that is was performed by the MD – heart and lungs “within normal limits” per medical assistant.

Patient ID 8055

Age 45

ASA II

Liposuction and abdominoplasty

2-25-15

General Anesthesia

Dr. McAdoo

Consents missing specific procedure within the body of the consent. Consents missing specific anatomical areas for liposuction. Consent missing verbiage for 64B15 as physician is an osteopath. Immediate preoperative assessment documented by medical assistant and signed by MD without indication that is was performed by the MD – heart and lungs blank. Consent has both CRNA and MD as anesthesia provider. Missing EKG preop on ASA II age 45.

Patient ID 71039

Age 36

ASA II

Liposuction

7-6-15

General Anesthesia

Dr. McAdoo

Consent missing verbiage for 64B15 as physician is an osteopath. Consents signed day of surgery must be timed.

Encore Plastic Surgery
1738 West 49 Street
Hialeah Fl 33012

03/04/2016 1,500.00
ID: 1025 Type: F
BT: 3016426
R#: 915043031

February 25, 2016

Dept of Health
Board of medicine
4052 Bald Cypress Way, BIM #D03
Tallahassee FL 32399
Office Surgery Department

RE: PLAN OF CORRECTION:

Encore Plastic Surgery:OSR# 857 1514
Location Address: 1738 West 49th Street Hialeah Fl 33012
Date of Inspection: 1/27/2016
Register physicians: Dr. Osak Omulepu ME99126, Dr. Orlando Llorente ME99849.
Conducted by: Rachelle Springer, RN LHCRM

As of January 27, 2016 the office surgery center has begun implementing the following deficiencies:

Estrella Rojas, Administrator of Encore Plastic Surgery is responsible for the corrective action and ongoing compliance.

The administrative staff, RN, surgeons and anesthesia personnel have been in serviced for the following deficiencies and shall maintain compliance with Chapter 458.309 Rule 64B8-9.0091, F.A.C.

Tag #5 The equipment meets the current performance standards: The refrigerator was re inspected by Mart Medical Equipment a sticker was placed. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance. See attached document.

Tag #7 Compliance with Pre-operative Records: Estrella Rojas meet with the all the staff and discussed the importance of the Pre-Operative sheet. Both the staff and Physicians understood that this page is only to be filled by the doctor. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance.

Tag #8 Compliance with Patient/Procedure Records: Estrella Rojas conducted a meeting with administration, and surgical staff to ensure all paperwork was done correctly. We discussed the importance of all recovery records. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance.

Tag #9 Compliance with Informed Consent: Estrella Rojas met with all O.R staff to ensure all consent forms signed the day of surgery are timed, we also discussed the importance of no cross outs without the patients initials or white outs in the patients' medical chart, staff was also made aware to place areas of liposuction and fat transfer on the surgery consents as well. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance.

WJL

Tag #10 Compliance with Surgical Logs: All Anesthesia logs were reviewed and re-written by the administration, all CPT codes and Adverse Incident are on site. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance. See attached document.

Tag #17 Compliance with anesthetic monitoring: Estrella Rojas met with Freitas CRNA and team manager Jesus Del Risco to ensure he understood the importance of monitoring each patient under general anesthesia every 5 minutes for blood pressure and heart rate. Also every 15 minutes for respiration, temperature, oxygen and saturation. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance

Tag #18 & 19 Compliance with policy and procedures manual/ risk management program: At the present time Encore Plastic Surgery chooses to perform quarterly assurance policies and risk management with all the doctors and employees on staff. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance

Tag #21 Compliance with signage: All Consents were reviewed and re-written to ensure all missing information was on site for all types of doctors performing surgery at our facility. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance. See Attached document.

Tag #22 Transfer Agreement Required or Hospital Staff Privileges: Attached is the letter of privileges for Dr. Osak Omulepu, at the time of the inspection the letter said no expiration date. See attached document.

Tag #26 Compliance with Equipment and Supplies Required: Our backup power was inspected by Mart Medical to ensure both O.R have back up power at the same time. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance. See attached documentation.

Tag #31 Compliance with the American Society of Anesthesiologist's Classification for appropriate candidates for level III office surgery. Estrella Rojas met with all O.R staff to ensure all patients 40 years old or older even if they are ASA I have EKG done prior to surgery. We have reviewed the new ASA classifications with all Doctors, Anesthesiologists and OR as well. It would be the responsibility of Estrella Rojas, administrator in maintaining the ongoing compliance. See attach document

Tag #33 Compliance with Emergency Procedures: Dr. Bass did not performed any cases on 2015, we did not know all register physicians needed to attend emergency drills if they were not doing cases. Estrella Rojas as administrator of Encore Plastic Surgery took the decision of taking Dr. Bass of from our register physicians, we will not be working at the facility for now, and we have notified the health department. See attached document.

On the day of the inspection we clarified with the inspector our current staff. We are notifying the State that based on our database the following registered physicians and clinical staff that are currently working at our facility:

Physicians: Dr. Osak Omulepu ME99126, Dr. Orlando Llorente ME99849.

CRNA/ARNPs: Jesus del Risco, Jason Vera, Sergio Hernandez, Gabriel Dietsch, Alexandra Cortes, Lourdes Dieguez, Richard Lauriello, Carolina Wilson, Christina Vera, Carlos de la Hoz, Richard Eckert, Peter Kandu, Huber Matos, Raquel Szkolnik, Carlos Freitas, Jhon Rutter, Javier Gonzalez, Lisa Ferrens, Javier Gonzalez, Jose Barrera, Gaig Luehrs, Fara Vazquez.

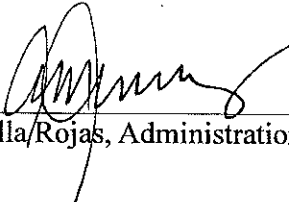
MD Anesthesia: Carlos Lazalle.

RN: Maritza Rodriguez, Nereida Rodriguez, Jacqueline Cuellar, Wendy Trujillo.

Surgical Assistants/Technologist: Cesar Martinez, Mitdael Moreno, Lester Trastoy, Mario Ledesma, Yaite Fernandez, Jose Ramon Jaime, Alberto Toledo, Jorge Fuerte, Klovys Castellanos, Jorge Reyes, Jose Manuel Ramagoza.

Circulators: Carolina Mourelo, Yanedys Arencibia, Lianys Blain, Graciela Rodriguez, Betsy Reyes, Aracelis Velazco.

I have read this Plan of Correction Report and affirm that the information given herein is true and correct to the best of my knowledge.



Estrella/Rojas, Administration



Date